

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BIAGIO RAVO and ENRICO NICOLO,)	
)	
Plaintiffs,)	Civil Action No. 2:11-cv-01637-JFC
)	
v.)	Judge Joy Flowers Conti
)	
COVIDIEN LP,)	
)	
Defendant.)	
)	

MEMORANDUM OPINION AND ORDER

The construction of the claims in dispute in the instant patent infringement action was set forth in the Report and Recommendation (ECF No. 48) filed by a special master (the “Special Master”). United States Patent No. 6,117,148 (the “‘148 Patent”), entitled Intraluminal Anastomotic Device, is held by Biagio Ravo and Enrico Nicolo (“plaintiffs”) and describes two embodiments of a surgical device that can be used to resect a section of bowel (or any hollow organ) through intussusception followed by anastomosis and in turn preventing the intraluminal contents from contaminating the body cavity. Plaintiffs and defendant Covidien LP (“Covidien” or “defendant”) objected to the recommended construction of certain claims in the ‘148 Patent.

The court reviewed the Special Master’s Report and Recommendation on claim construction, plaintiffs’ objections to the Report and Recommendation, (ECF No. 49), Covidien’s objections and partially unopposed motion to modify the Report and Recommendation, (ECF No. 50), Covidien’s response to plaintiffs’ objections to the Report and Recommendation (ECF No. 51), plaintiffs’ response to Covidien’s objections and partially unopposed motion to modify the Report and Recommendation, (ECF No. 52), and the

supplemental Report and Recommendation of the Special Master on claim construction, (ECF No. 53.)

While numerous terms were initially disputed, the objections relate to only six terms that remain in dispute: (1) “Anvil,” (2) “Stapling assembly,” (3) “Central post,” (4) “Relative movement between,” (5) “Luminal anastomosis means/Said anastomosis means” and (6) “Luminal attachment and intussusception means.” The court will address de novo each remaining disputed term in turn.

I. Legal Standard

Claim Construction

Proper claim construction looks first and foremost to the “intrinsic evidence,” i.e., the patent’s claim language, specification, and prosecution history, to determine the meaning of disputed claim terms. Phillips v. AWH Corp., 415 F.3d 1303, 1311-17 (Fed. Cir. 2005) (en banc). The words of a claim “are generally given their ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” Id. at 1312-13 (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed Cir. 1996); Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1116 (Fed. Cir. 1994)). The Court of Appeals for the Federal Circuit explained in Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313 (Fed. Cir. 2005), that “[w]e cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.” Medrad, Inc., 401 F.3d at 1319. The court emphasized that “the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” Phillips, 415 F.3d at

1315 (quoting Vitronics, 90 F.3d at 1582). Courts should therefore “rely heavily on the written description for guidance as to the meaning of the claims.” Id. at 1317.

While claims are to be construed in light of the specification, courts must be careful not to read limitations from the specification into the claim. Id. at 1323. Thus, if a patent specification describes only a single embodiment that does not mean that the claims of the patent necessarily must be construed as limited to that embodiment. Id. The purpose of the specification is “to teach and enable those of skill in the art to make and use the invention” and sometimes, the best way to do that is to provide an example. Id. In Phillips, the Court of Appeals for the Federal Circuit acknowledged that “the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice.” Id. The court of appeals emphasized that “the line between construing terms and imparting limitations can be discerned with reasonable certainty and predictability if this court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.” Id.

In addition to relying on the specification, a court may also consider the patent’s prosecution history, which is part of the intrinsic evidence, and “consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” Id. at 1317. Although the prosecution history “often lacks the clarity of the specification and thus is less useful for claim construction purposes,” it nonetheless “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” Id. For example, an applicant limits claim scope during prosecution by a “clear disavowal of claim coverage, such as an amendment to

overcome a rejection.” Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1327 (Fed. Cir. 2003) (citing York Prods., Inc. v. Central Tractor Farm & Fam. Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996)).

Finally, a court during claim construction may consider “extrinsic evidence, which ‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” Phillips, 415 F.3d at 1317 (quoting Markman, 52 F.3d at 980). Nonetheless, extrinsic evidence is generally less reliable than intrinsic evidence and must always be considered in the context of the intrinsic evidence. Id. at 1318-19.

II. Remaining Disputed Claim Terms

A. Anvil

The term “anvil” is used in claims 5 and 13. The parties’ main dispute over the construction of “anvil” is whether the supporting shaft should be included within the claim construction. Covidien argues that “anvil” should be construed to include the supporting shaft because the specifications refer to an anvil member and the shaft is necessary for the movement of the anvil member relative to the staple driver. (ECF No. 50 at 2.) Plaintiffs, however, explain that the shaft is referred to as the central post in the first embodiment and the central rod in the second embodiment and are named differently because each has a slightly different purpose. (ECF No. 52 at 4.) Plaintiffs argue that “[i]f, as Covidien contends, the shaft were part of the anvil, there would have been no reason to give the item a separate name in the second embodiment because the anvil is shown and labeled in both the first and second embodiments.” Id.

The court is persuaded by plaintiffs' argument because the common, ordinary meaning of the term "anvil," as well as the use of the term in conventional structures such as similar end-to-end anastomosis staplers indicates that the anvil does not include the supporting shaft. (ECF No. 48 at 22 n. 5.) Additionally, the shaft is referred to as a separate element within the '148 Patent. Thus, "anvil" will be construed as a "member against which staples are bent." The court adopts the construction set forth in the Special Master's Report and Recommendation. (ECF No. 48-2.)

B. Stapling Assembly

The "stapling assembly" is described within the '148 Patent and is supported by the customary meaning of the word "assembly" (*Phillips*, 415 F.3d at 1314); an assembly is made up of only the parts involved in that function, here stapling. Defendant objects to the Special Master's recommended construction for this term because it does not include a reference to a supporting shaft. Defendant, however, provides no additional argument for its position. (ECF No. 50 at 3.) Plaintiffs do not dispute the Special Master's construction of "stapling assembly." The portion of the '148 Patent describing the "stapling assembly" can be found at Col. 5 lines 63-66:

The anvil member 58 and stapling head 60 combine to form a stapling assembly 61 which is movable relative to at least the annular groove 56 of the housing 52 as will be described hereinafter.

'148 Patent col. 5 l. 63-66 (filed Oct. 16, 1998). (emphasis added) The court concludes that the construction set forth in the Special Master's Report and Recommendation is correct: "stapling assembly" will be construed as the "stapling head and anvil." (ECF No. 48-2.)

C. Central Post

The dispute over the construction of the term "central post" depends upon which section of the patent (specification or claims) must be relied upon for determination of the proper

construction of the term. Both the Special Master and defendant quote sections of the patent specification where the central post is movable compared with the anvil member or annular housing. (ECF No. 48 at 25 and ECF No. 51 at 7.) They argue that this movement, which is described within the specification and which they believe to be demonstrated within Figures 1 and 2, must be included in the term construction. (ECF No. 51 at 7.)

Plaintiffs' argument, however, is more persuasive with respect to the term "central post" since plaintiffs rely upon the plain meaning used within the claims themselves. Defendant and the Special Master rely too heavily on the specifications to construe the term "central post." The United States Court of Appeals for the Federal Circuit has held that the court is to "'look to the words of the claims themselves ... to define the scope of the patented invention.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "'The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995)).

Plaintiffs explain that "[t]he Report and Recommendation chooses to ignore this plain definition in the '148 Patent specification and instead reads extra limitations into the simple term 'central post'." (ECF No. 49 at 9.) They provide three reasons why relative movement should not be read into the construction of the term "central post": claim 2 adds the limit of movement, claim 16 refers to a "movable central post," and claim 3 refers to the central post as a structural term without any inference to movement. The court concludes the plain language of the claims contemplates that movement is not part of the construction of "central post." Under that

analysis, “central post” will be construed as a “structure extending along a central axis of the housing.” (ECF No. 49 at 10.)

D. Relative Movement Between

The phrase “relative movement between said stapling assembly and said luminal attachment member operates to invert a portion of the lumen” is used in asserted claim 15. Claim 15 describes how intussusception of the bowel will occur in the second embodiment. Intussusception can only happen through the movement of the luminal attachment member with respect to the stapling assembly.

Defendant would like to include the word “entire” in reference to the stapling assembly and the word “separate” in reference to the luminal attachment member. (ECF No. 50 at 3.) Defendant argues that its “construction more clearly precludes asserted claim 15 from covering every circular stapler with a groove in the anvil shaft, including many conventional circular staplers that preclude the ‘148 patent.” (ECF No. 50 at 3-4.) Plaintiffs argue that the “movement of the central post with respect to the housing and stapling head within the housing is necessary for the function of inverting the lumen. In contrast, movement of the central post relative to the anvil is totally irrelevant to both attachment of the lumen and intussusception of the lumen.” (ECF No. 52 at 8.)

The court agrees with plaintiffs and the construction of the Special Master that the inclusion of the words “entire” and “separate,” as suggested by defendant, are not required for the construction to be clear. “Relative moment between” refers to “the stapling assembly and the luminal attachment member are moved relative to one another to cause intussusception.” The court adopts the construction set forth in the Special Master’s Report and Recommendation. (ECF No. 48-2.)

E. Luminal Anastomosis Means/Said Anastomosis Means

Means-plus-function limitations are governed by 35 U.S.C. § 112, which requires that description of both function and the associated structure be provided. Additionally, when more than one embodiment exists, as in this case, means-plus-function limitations may need to be described separately for each embodiment. Ishida Co. Ltd. v. Taylor, 221 F.3d 1310 (Fed. Cir. 2000).

The parties agree that the function associated with “luminal anastomosis means/said anastomosis means” shall be construed as “for attaching the lumen wall together prior to completion of resection.” (ECF No. 48-2.)

The structure associated with “luminal anastomosis means/said anastomosis means,” however, is disputed. Defendant objects to not having the reference to the supporting shaft after anvil. (ECF No. 50 at 3.) It believes that “the anvil shaft is a necessary component of luminal anastomosis means and the corresponding structure for both embodiments must include the anvil shaft.” (ECF No. 38 at 22.) The Special Master states: “Covidien’s proposed use of the term ‘anvil’ is consistent with Covidien’s proposed construction for that term. The undersigned [does] not agree with Covidien, though, as to the need to associate an anvil shaft with an anvil.” (ECF No. 48 at 32.) The court agrees with the Special Master in reference to the construction of anvil and again here with the construction of anvil within the construction of the phrase “luminal anastomosis means/said anastomosis means.”

Neither party objected to the separate constructions produced by the Special Master for each embodiment. The method of anastomosis is described within the ‘148 Patent for embodiment #1 at Column 4 lines 47-51:

Following the clamping of the annular housing **20** against the anvil member **18**, the staples in the staple row **22** are fired, and the annular knife **24** is radially

advanced against the anvil member **18** to sever the intussuscepted portion of the bowel.

‘148 Patent col. 4 l. 47-51. In embodiment #1, after intussusception, the staple row is driven radially to connect the two portions of the lumen wall. Therefore, embodiment #1 will be construed as “an anvil and a housing with staple rows that are driven radially along the width of the device.” (ECF No. 38 at 21.) Embodiment #2, however, works to connect the two portions of the lumen wall after it has been intussuscepted through a longitudinal movement of the staple rows. The ‘148 Patent describes the anastomosis used in embodiment #2 and explicitly states that it is different from embodiment #1:

Staple rows **62** and annular knife **64** differ significantly from staple rows **22** and annular knife **24** of surgical tool **10** in that the staple rows **62** and annular knife **64** operate along the longitudinal length of the surgical tool **50** in the same manner as conventional end-to-end anastomosis stapling devices.

‘148 Patent col. 6 l. 6-11. As such, embodiment #2 will be construed as “an anvil and a stapling head with staple rows that are driven longitudinally along the length of the device.” (ECF No. 38 at 21.) The court agrees that the inclusion of the word “member” is unnecessary after anvil in either case since “anvil” was previously construed and, as pointed out by defendant, “anvil member” is not defined. (ECF No. 50 at 5.) The Special Master in his Supplemental Report and Recommendation on Claim Construction acknowledges this point. (ECF No. 53 at 3.)

F. Luminal Attachment and Intussusception Means

The phrase “luminal attachment and intussusception means” is asserted in claims 1, 2, 3 and 11. The parties agree “luminal attachment and intussusception means” should be construed to have two functions: attaching and intussuscepting. (ECF No. 48 at 33.) As previously discussed when referring to the tissue that is to be removed, “lumen wall” must be used. Neither party disagrees with the Special Master’s construction. (ECF No. 48 at 33.) Therefore, the

function of “luminal attachment and intussusception means” will be construed as “1) for attaching a portion of the lumen wall to be removed; and 2) for inverting a portion of the lumen wall to be removed.” The court adopts the construction set forth in the Special Master’s Report and Recommendation. (ECF No. 48-2.)

Both parties agree that the structure for “luminal attachment and intussusception means” should be construed for each embodiment. (ECF No. 48 at 34.) Each embodiment describes the location of the annular groove in a different place, providing the need for two separate constructions. In embodiment #1 the annular groove is located on the central post and embodiment #2 places the annular groove on the housing.

Plaintiffs argue that the construction should include reference to a ligation member such as a band or sutures. They provide references within the ‘148 Patent which “indicate that the structure corresponding for the performing the function of ‘attachment of the portion of the lumen’ is the central post having an annular groove and a ligation member such as a band or sutures, and equivalents thereof.” (ECF No. 49 at 7.) Defendant argues that “[t]he Special Master correctly found that the specification does not disclose a ligation member that is ‘coupled to the housing’ as required by the claims.” (ECF No. 51 at 14) It argues that “the ligation members disclosed in the ‘148 Patent never touch the device because they are compressing tissue between themselves and the disclosed embodiments.” Id.

The court agrees with the Special Master that the analysis in Ravo v. Ethicon Endo-Surgery, Inc., No. 04-617, 2005 WL 6217118, *4-6 (W.D. Pa. Nov. 17, 2005), is persuasive with respect to the structure of “luminal attachment and intussusception means.” “‘Band or sutures’ are only ‘coupled’ to the housing after placement. Before placement, they exist separate from and are not ‘coupled’ to the housing – therefore, they are not part of corresponding structure.”

(ECF No. 48 at 36) (citing Ravo v. Ethicon Endo-Surgery, Inc., No. 04-617, 2005 WL 6217118 (W.D. Pa. Nov. 17, 2005)). As such, the reference to bands or sutures will not be included in the construction.

Finally, the necessary movement between the parts of the device must be addressed. Just as the movement must occur between the housing and stapling assembly for intussusception to occur in embodiment # 2, movement must occur between the central post and the housing in embodiment # 1.

Defendant argues that the movement of the central post must be included within the construction of the term “central post”. The court, however, agreed with plaintiffs that the movement should be left out of the construction of the structural term “central post.” As such, that movement within embodiment #1, which includes the central post, must be provided for within the construction of “luminal attachment and intussusception means.” Under these circumstances, the court will insert the phrase “independently movable with respect to”, which was suggested by defendant, in the construction of “central post” and place it into embodiment # 1. This construction differs from the construction proposed by defendant and the Special Master with respect to embodiment #1. (ECF No. 48 at 36.) Defendant and the Special Master would leave the movement out of this construction because they would have included it within the “central post” construction. Defendant argues in footnote 7 of its opening brief in support of proposed interpretations of claims, “[t]o the extent this Court does not adopt this language as part of the definition of ‘central post’, it should be incorporated directly into defined structure for ‘luminal attachment and intussusception means’.” (ECF No. 38 at 27 n. 7.) The court did not construe movement in the term “central post” and will construe movement to be included in both embodiments for “luminal attachment and intussusception means.”

The claim in embodiment #1 will be construed as “an annular groove located on the central post and independently movable with respect to a housing over or around which the lumen *wall* is inverted.” The court inserted the word “wall” after “lumen” relying upon the discussion by the Special Master, which is undisputed by the parties, that the word “lumen” refers to the empty space within the tubular organ, since this construction refers to the “lumen wall” that is to be inverted, not the empty space. (ECF No. 48 at 14.)

The movement within embodiment # 2 was included within the construction by the Special Master. Embodiment #2 will be construed as “an annular groove located on the housing and a stapling assembly that move relative to one another.” The court adopts this construction as set forth in the Special Master’s Report and Recommendation. (ECF No. 48-2.)

ORDER

AND NOW, this 27th day of June, 2013, for the reasons set forth above, it is HEREBY ORDERED that the Special Master’s Report and Recommendation (ECF No. 48) is adopted except to the extent noted otherwise.

IT IS FURTHER ORDERED that:

I. Agreed Upon Terms

Plaintiffs and defendant agreed upon the construction of three terms, and those terms shall be construed as follows:

1. “Anastomosis” is a “surgical connection between two portions of the lumen wall.” (ECF No. 46.)
2. “Lumen” is the “cavity of a tubular organ. It is not limited to the bowel.” (ECF No. 46.)
3. “Resection” refers to “surgical removal.” (ECF No. 46.)

II. Undisputed Terms

The Special Master construed the following term and his construction was not disputed in the objections and those terms shall be construed as follows:

1. “Attachment” is “fastening,” “Attached” is “fastened,” and “Attaching” is “fastening.” (ECF No. 48-2.)
2. “Intussusception” is the “surgical pulling of the lumen wall inside itself” and “Intussuscepted” is the “lumen wall surgically pulled inside itself.” (ECF No. 48-2.)
3. “Luminal attachment Member” refers to the “annular groove in a structural member.” (ECF No. 48-2.)
4. “Portion of the lumen/Lumen portion” refers to a “portion of the lumen wall.” (ECF No. 48-2.)
5. “Resection Means” being a means-plus-function term requires a construction of the term in both a function and a structure form. The function is construed as: “for severing the intussuscepted portion of the lumen wall after the anastomosis without opening the lumen.” The structure is construed separately for both embodiments. Embodiment #1 is an “annular knife” and embodiment #2 is an “annular knife or severing wire surrounding the stapling head.” (ECF No. 48-2.)

III. Disputed Terms

As discussed above six terms were disputed in the objections, the court construes those terms as follows:

1. “Anvil” is a “member against which staples are bent.” (ECF No. 48-2.)
2. “Stapling Assembly” is the “stapling head and anvil.” (ECF No. 48-2.)
3. “Central Post” is a “structure extending along a central axis of the housing.” (ECF No. 49 at 10.)
4. “Relative Moment Between” shall be “the stapling assembly and the luminal attachment member are moved relative to one another to cause intussusception.” (ECF No. 48-2.)
5. “Luminal Anastomosis Means/Said Anastomosis Means” being a means-plus-function term requires a construction of the term in both a function and a structure form. The function shall be: “for attaching the lumen wall together prior to completion of resection.” (ECF No. 48-2.) The structure is construed separately for both embodiments. Embodiment #1 is “an anvil and a housing with staple rows that are driven radially along the width of the device.” (ECF No. 38 at 21.) Embodiment #2 is “an anvil and a stapling head with staple rows that are driven longitudinally along the length of the device.” (ECF No. 38 at 21.)
6. “Luminal Attachment and Intussusception Means” being a means-plus-function term requires a construction of the term in both a function and a structure form. The function shall be: “1) for attaching a portion of the lumen wall to be removed; and 2) for inverting a portion of the lumen wall to be removed.” (ECF No. 48-2.) The structure is construed separately for both embodiments. Embodiment #1 is “an annular groove located on the central post and independently movable with respect to

a housing over or around which the lumen wall is inverted.” Embodiment #2 is “an annular groove located on the housing and a stapling assembly that move relative to one another.” (ECF No. 48-2.)

BY THE COURT,

/s/ Joy Flowers Conti
JOY FLOWERS CONTI
UNITED STATES DISTRICT JUDGE